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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/245,277	02/05/1999	PAUL P. WORLEY	JHU1530-3	4724

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 02/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/245,277	WORLEY ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64-68 and 70-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64-68 and 70-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 06, 2004 has been entered.

Response to Amendment

2. Claims 70-71 have been amended and claims 62-63 have been cancelled as requested in the amendment of Paper filed on December 06, 2004. Claims 62-68 and 70-72 are pending in the instant application.

Claims 64-68 and 70-72 are under examination in the instant office action.

3. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on December 06, 2004 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Objections

6. Claim 64 is objected to because of the following informalities: claim 64 depends from a cancelled claim. Appropriate correction is required.

Claim Rejections - 35 USC § 101

7. Claims 65-68 and 70-72 stand rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for reasons of record in section 3 of Paper No. 29 and also in section 3 of Paper mailed on March 08, 2004. Briefly, the instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder or physiological process, which one would wish to manipulate for a desired clinical effect.

Applicant traverses the rejection on the premises that "the specification clearly discloses specific and substantial utilities for the inventive nucleic acids and polypeptides, including their use as markers of seizure events in neuronal tissue" (bottom at page 4 of the Response). Applicant further explains three experimental models of seizure induction, in which the gene expression of the claimed isolated nucleic acid molecules was elevated (page 5 of the Response). Applicant further provides more explanation regarding the validity of the used models of seizure induction to study brain function, "the disclosed experimental models are well-known and validated models for studying seizure and epilepsy. Therefore, absent evidence to the contrary, Applicants submit that there is no reason to believe that the inventive nucleic acids and polypeptides are not useful as markers of seizure events in neuronal tissue" (bottom at page 6). Applicant also points out that the instant specification discloses the ability of the L100 protein encoded by the claimed nucleic acids to sequester zinc *in vivo,* and that "release and uptake of Zinc may participate in the induction and maintenance of epileptic seizures and the neuronal

death following epileptic seizures and ischemia" (top at page 7). Applicant's arguments have been carefully considered but are not deemed to be persuasive for the reasons that follow.

The Court in *Brenner v. Manson* held that "[t]he basic *pro quid quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point – where specific benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

Applicant submits that characterization of the claimed nucleic acids as being up-regulated during experimentally induces seizures is sufficient to establish their utility. However, one skilled in the art readily appreciates that during experimental "shock", such as during MECS (maximum electroconvulsive seizure) or exposure to certain chemical substances (kainate or PTZ treatment), cellular metabolism would naturally be expected to be changed, which would result in up- or down-regulation of certain genes. The Examiner never disputed that the instant claimed nucleic acids could belong to the class of IEG, immediate early genes. However, it is well known in the art that IEG "encode a variety of polypeptides including transcription factors, cytoskeletal polypeptides, growth factors, and metabolic enzymes as well as polypeptides involved in signal transduction" (bottom at page 1 of the instant specification, for example). In the absence of the biological significance of these particular claimed nucleic acids, the information that the nucleic acid molecules of SEQ ID NO: 26 or SEQ ID NO: 27 are expressed immediately following seizure does not provide for their specific, substantial and credible utility. Furthermore, the record does not support Applicant's position that the characterization of a

nucleic acid, which is upregulated during experimental seizure, is useful as a marker for seizures in neuronal tissues. As fully explained in the previous office actions of record, in order to be considered a marker for any pathological condition, the claimed polynucleotide must be either present or absent in the diseased tissue versus healthy tissue or to be present at the specific altered levels that are directly associated with that condition. The instant specification, as filed, provides no meaningful guidance that would allow those skilled in the art to use the claimed polynucleotides in this specific way.

Thus, the record does not support Applicant's position that the characterization of a nucleic acid as being upregulated during experimental seizure would have suggested a specific biological function, or any other basis for patentable utility, to a person skilled in the art at the time the application was filed. In the terms used by the *Brenner* Court, such a characterization does not provide a specific utility in currently available form. Applicant claims a product asserted to be useful in marking neuronal seizures but the specification does not disclose how to interpret those data. Just as the process claimed in *Brenner* lacked utility because the specification did not disclose how to use the end-product, the product claims here lack utility, based on their use, e.g. markers for neuronal seizures, because the specification does not disclose how to use the SEQ ID NO: 26 or 27 specific gene expression.

Thus, for reasons of record in the previous office action and reasons explained above, the instant rejection is maintained.

Claim Rejections - 35 USC § 112

8. Claims 65-68 and 70-72 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a clear asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

9. Claims 66-68 and 70-71 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in section 5 of Paper No. 29 and in section 7 of Paper mailed on March 08, 2004.

Applicant argues that "the present disclosure recites a full-length nucleic acid sequence of SEQ ID NO: 26, which can increase expression upon seizure induction and can influence neuronal activities involved in brain function [...]. From this disclosure, one skilled in the art could readily determine the structures of nucleic acids with structures that are at least 60 percent identical or at least 85 percent identical" (bottom at page 8, continuing to page 9 of the Response). Applicant further submits that "the skilled artisan would recognize that Applicants were in possession of the claimed nucleic acid sequences because the specification provides a detailed description of methods to screen such nucleic acid sequences for expression responsive to stimulus such as seizure or ischemia" (last paragraph at page 9). Applicant's arguments have been fully considered but are not persuasive for the following reasons.

It appears that Applicant has taken the position that 35 U.S.C. 112, first paragraph, permits an artisan to present claims, which encompass essentially any compound with limited structural similarity to the disclosed molecular embodiment as long as the specification provides one with the ability to test any particular embodiment, which is encompassed by the material limitations of a claim and thereby distinguish between those embodiments which meet the functional limitations from those embodiments which don't. As fully explained in the previous office actions of record, to provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. It is not the ability of one skilled in the art to make and test if a compound, which has 90% structural similarity to the instant nucleic acid of SEQ ID NO: 26, "can influence neuronal activities involved in brain function" that satisfies "the 'written description' inquiry, *whatever is now claimed.*" (*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, page 1117.) . It is the specification that must "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). In the instant case, the instant specification provides no disclosure of complete or partial structure of the claimed nucleic acids, physical and/or chemical properties or structure/function correlation, therefore, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of nucleic acids. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, for reasons of record in previous office actions and reasons explained above, the rejection of the instant claims is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 64 depends from the cancelled claim; therefore, the metes and bounds of the claimed subject matter cannot be determined.

Conclusion

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax

center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1646

February 11, 2005